DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS)

1. Technology Name: X STOP
Interspinous Process Decompression Implantable Device

2. Manufacturer Name: St. Francis Medical Technologies, Inc.

3. Trade Brand of Technology: X STOP Interspinous Process Decompression System

4. Brief Description of Service or Device:

A new minimally invasive, stand-alone alternative treatment for lumbar spinal stenosis has been developed. The X STOP is placed between the spinous processes to limit extension of the symptomatic level(s), yet allowing flexion, axial rotation and lateral bending. This provides a potential alternative to conservative and surgical treatments.

New Criteria

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

SFMT anticipates that a PMA Approval Order for the X STOP device will be issued by the FDA before the end of 2005.

6. Was the product available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation for any delay (i.e. manufacturing issues, shelf life concerns or other reasons).

SFMT anticipates the X STOP device will be available on the market immediately after FDA issues an approval order.

7. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?

a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

YES
84.58 Implantation of Interspinous process decompression device
Excludes: fusion of spine (81.00-81.08, 81.30-81.39)

b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to http://www.cms.hhs.gov/paymentsystems/icd9 for more information.) We note that, if the product were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-9-CM code(s) in the MedPAR claims data in order to receive add-on payment.

8. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. (Please refer to http://cms.hhs.gov/providers/hopps/apc.asp for more information.)

St. Francis Medical Technologies will be submitting an application for outpatient pass-through payments under OPPS before 12/30/05. However, at this time, no application has yet been filed.

(For the complete application requirements, please see the instructions at http://cms.hhs.gov/providers/hipps/10_04_application.zip)

Note: The information provided on this tracking form will be made publicly available.

Cost Criteria

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by DRG. The most recent version of Table 10 can be downloaded at: http://www.cms.hhs.gov/providers/hipps/newtech.asp.

Provide the following information to demonstrate the technology or service meets the criterion.

9. What is the anticipated average standardized charge per case involving this new technology? For details how to standardize charges please refer to the technical appendix of the application form.

TAC = Total Charges/(1+IME Operating Adj Factor + DSH Oper Adj Factor)
TAC ={$13,353 / (1 + 1.0966164 + 0.0461658)} + 1.272*{1.6($5,500)}
TAC = $11,684.64 + $11,193.60
TAC = $22,878.24

**Denotes hospital's CCR value for device charge with cost of $5,500 per unit, and 1.6 units per case.*

SC = {(TAC * .711)/Wage Index Value) + (TAC * .289)/COLA)}
SC = {($22,878.24 * .711)/1.3784) + ($22,878.24 * .289)/1)}
SC = {($16,266.43/1.3784) + ($6,611.81/1)}
SC = $11,800.95 + $6,6,11.81
SC = $18,412.76 – Year 2000

Standardized Charge for 2001:	$19,628.00
Standardized Charge for 2002:	$21,237.50
Standardized Charge for 2003:	$22,617.94
Standardized Charge for 2004:	**$24,065.48**

10. What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)? What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. **Drugs**- Average dosage or number of units per patient (ml/kg/hr); **Devices**- breakdown of the cost of all components used in the new technology, clearly showing which components are the "new" ones).

1.6 units per case
$5,500.00 per unit
$8,800.00 per case

The X STOP device and implant tools are issued on a 'per level' basis. The charge to the purchasing entity is $5,500 per level.

11. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned.

499	Back and Neck Procedures Except Spinal Fusion with CC
500	Back and Neck Procedures Except Spinal Fusion without CC

12. What is the anticipated volume of Medicare cases involving of this technology in FY 2007 (by DRG)?

2,121 Medicare cases total

DRG 499	424 (approximately)
DRG 500	1697 (approximately)

Clinical Improvement

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services.

13. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.

a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

Use of the X STOP device significantly improves clinical outcomes compared to conservative, nonoperative therapies (e.g., epidural steroid injections and pain medications), and may offer a new alternative to lumbar spinal decompression procedures (e.g., laminectomy, laminotomy). The X STOP preserves spinal motion as oppposed to a spinal decompression procedure that requires concomitant fusion (with or without instrumentation). Advantages over nonoperative care include better symptom relief, improved function and increased patient satisfaction while the advantages over spinal decompression include reduced risk, shorter hospital stay, and earlier improvement in pain and function. In addition, by allowing motion at the treated level the risk of long-term (e.g., 10-year) disease progression at adjacent levels is minimal following X STOP implantation compared to the known risk associated with surgical decompression and concomitant fusion.

In addition, the X STOP is comparable to traditional surgical decompression of lumbar spinal stenosis with respect to improved quality of life postoperatively. Although the SF-36 results suggest that the X STOP is comparable to lumbar decompression, the outcomes measures do not reflect the additional benefits offered by the X STOP technique. The X STOP procedure is typically performed under local anesthesia, does not generally require removal of any bony tissue, and is relatively pain-free compared to other more invasive techniques, which allows for a faster recovery.

b. List of published peer-review articles relevant to the new service or technology.

Biomechanical Manuscripts

1. Fuchs, P.D., et al., *The use of an interspinous implant in conjunction with a graded facetectomy procedure.* Spine, 2005. **30**(11): p. 1266-72; discussion p. 1273-4.
2. Lindsey, D.P., et al., *The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine.* Spine, 2003. **28**(19): p. 2192-7.
3. Richards, J.C., et al., *The treatment mechanism of an interspinous process implant for lumbar neurogenic intermittent claudication.* Spine, 2005. **30**(7): p. 744-9.
4. Swanson, K.E., et al., *The effects of an interspinous implant on intervertebral disc pressures.* Spine, 2003. **28**(1): p. 26-32.
5. Talwar, V., et al., *Insertion loads of the X STOP interspinous process distraction system designed to treat neurogenic intermittent claudication.* Eur Spine J, 2005, **On-Line**.
6. Wiseman, C.M., et al., *The effect of an interspinous process implant on facet loading during extension.* Spine, 2005. **30**(8): p. 903-7.

Clinical Manuscripts and Book Chapters

7. Gunzburg, R. and M. Szpalski, *The conservative surgical treatment of lumbar spinal stenosis in the elderly.* Eur Spine J, 2003. **12 Suppl 2**: p. S176-80.
8. Gunzburg, R. and M. Szpalski, *Lumbar Spinal Stenosis: Clinical Features and New Trends in Surgical Treatment.* Geriatric Times, 2004. **5**(4): p. 11-13.
9. Heijnen, S. and F. Kramer, *Spinal Distraction as Therapy for Lumbar Spinal Stenosis - The First Results.* Dutch Orthopedic Journal, 2005: p. 199-203.
10. Lee, J., et al., *An interspinous process distractor (X STOP) for lumbar spinal stenosis in elderly patients: preliminary experiences in 10 consecutive cases.* J Spinal Disord Tech, 2004. **17**(1): p. 72-7; discussion 78.
11. Zucherman, J., et al., *A Multicenter, Prospective, Randomized Trial Evaluating the X STOP® Interspinous Process Decompression System for the Treatment of Neurogenic Intermittent Claudication: Two Year Follow-Up Results.* Spine, 2005. **30**(12): p. 1351-8.
12. Zucherman, J. and J. Silverman, *Managing Spinal Conditions in Older Persons.* J Musculoskel Med, 2005. **22**: p. 214-22.
13. Zucherman, J.F., et al., *A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X STOP interspinous implant: 1-year results.* Eur Spine J, 2004. **13**(1): p. 22-31.
14. Zucherman, J.F., et al., A Multicenter, Prospective, Randomized Trial Evaluating the X STOP Interspinous Process Decompression System for the Treatment of Neurogenic Intermittent Claudication: Two-Year Follow-Up Results. Spine, 2005. **30**(12): p. 1351-8.

(For the complete application requirements, please see the instructions at http://cms.hhs.gov/providers/hipps/10_04_application.zip**)**

Note: The information provided on this tracking form will be made publicly available.